REMARKS

A. Status of the Application

Claims 1-9 and 11-13 were pending at the time of the last Office Action. Claims 1, 11, and 13 have been amended. Claim 2 has been cancelled. No claims have been added. Therefore, claims 1, 3-9, and 11-13 remain pending.

B. Claim Objection

Claim 11 is objected to as depending from cancelled claim 10. Applicants have amended claim 11 such that it depends from independent claim 1. Therefore the objection is overcome, and withdrawal of the objection is respectfully requested.

C. Section 101 Non-Statutory Subject Matter Rejection

Claims 1-9 and 11-13 stand rejected under 35 U.S.C. § 101 for all allegedly being directed to non-statutory subject matter. The Office alleges:

> In the instant case, the claimed method steps describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic "abstract idea." Specifically, the claimed method recites mathematical and/or statistical manipulations of data representing expression profiles. . . . The claimed method does not transform or reduce an article or a physical object to a different stage or thing because the "result" of the method . . . is merely data (gene expression information) and is not equivalent to physical transformation. The claims to not recite tangible expression (*i.e.* real world result) of classifying expression information, nor any recitation of an actual (*i.e.* concrete) result in a form useful to one skilled in the art.

Office Action at 3. (citations and internal quotes omitted). The Office concludes that "the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory." *Id.* Applicants respectfully traverse.

1. The Standard for Statutory Subject Matter Under 35 U.S.C. § 101

Federal Circuit precedent dictates that a claim directed to a machine that produces a useful, concrete, and tangible result is not excluded from patenting by 35 U.S.C. §101, even if a mathematical algorithm is a part thereof. *See State Street Bank and Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) and *In re Alappat,* 33 F.3d 1526 (Fed. Cir. 1994). The *State Street* and *Alappat* rules also apply to method claims. *AT&T Corp. v. Excel Communications Inc.* 172 F.3d 1352, 1357-58 (Fed. Cir. 1999)

("Whether stated implicitly or explicitly, we consider the scope of § 101 to the same regardless of form – machine or process – in which a particular claim is drafted."). Accordingly, systems and methods that produce useful, concrete, and tangible results are not excluded from patentability by 35 U.S.C. § 101.

The Federal Circuit explained in *Alappat* that the proper inquiry for patentability of claims containing mathematical subject matter calls for the determination of whether the claims produce mere abstract results or whether the claims have practical application:

> [A]t the core of Court's analysis . . . lies an attempt by the Court to explain a rather straightforward concept, namely, that certain types of mathematical subject matter, standing alone, represent nothing more than abstract ideas until reduced to some type of practical application, and thus that subject matter is not, in and of itself, entitled to patent protection.

Alappat, 33 F.3d at 1534 (emphasis added). In holding that a means for creating a smooth waveform display was patentable subject matter, the *Alappat* court stated "[t]his is not a disembodied mathematical concept that may be characterized as an 'abstract idea,' but rather a specific machine to produce a useful, concrete, and tangible result." *Id.* at 1544. The Federal Circuit further explained in *AT&T:*

> [T]he Alappat inquiry simply requires an examination of the contested claims to see if the claimed subject matter as a whole is a disembodied mathematical concept representing nothing more than a "law of nature" or an "abstract idea," or if the mathematical concept has been reduced to some practical application rendering it "useful."

AT&T, 172 F.3d at 1357 (emphasis added). Therefore, the proper "useful, concrete, and tangible results" inquiry of the patentability of the present claims under 35 U.S.C. § 101 is an examination of whether the claimed subject matter presents a non-abstract, practical application. *See Diamond v. Diehr*, 450 U.S. 175, 191 (1981) ("[W]hen a claim recites a mathematical formula (or scientific principle or phenomenon of nature), an inquiry must be made into whether the claim is seeking patent protection for that formula in the abstract."); *State Street Bank*, 149 F.3d at 1373 n. 4 ("[T]he mathematical algorithm is

unpatentable only to the extent that it represents an abstract idea.") and at 1375 ("The question of whether a claim encompasses statutory subject matter should . . . focus on . . . the essential characteristics of the subject matter, in particular, its practical utility."); *AT&T*, 172 F.3d at 1360 ("[O]ur inquiry here focuses on whether the mathematical algorithm is applied in a practical manner to produce a useful result.").

2. A Useful Result Is Produced.

Embodiments of this application relate to statistical methods of comparative analysis of gene data. Application at [0028]. "Analysis of data from large-scale mRNA expression studies is nontrivial due to the complexity and size of data sets and the fact that technical variation can be introduced at differing stages in array production and processing." Application at [0006]. Prior progressive statistical approaches "have been cogently criticized on a number of grounds, including the influence of outliers . . . on the parameters of linear regression, principal axis choice, and the absence of information about variability of individual expression levels within homogenous groups of samples." *Id.* Recognized standards have not resulted from prior art efforts to restrict the influence of outliers. *Id.* Furthermore, prior art methods "do not adequately address the mutually exclusive characteristics of sensitivity and specificity." *Id.* at [0007]. Embodiments of this application provide useful and novel procedures to address these recognized needs. The classification of differentially expressed genes as "likely false positive," "real positives," or "potential positives" is a useful result with practical utility.

3. A Tangible, Concrete Result Is Produced.

The Office's position that no tangible, concrete result is produced by the claimed methods appears to be based on the Office's assertion that the claimed methods do not present classification of differentially expressed genes in a form useful to one skilled in the art. Office Action at 3. Applicants do not acquiesce to this assertion. However, in

the interest of advancing prosecution of this case and gaining expeditious allowance of the pending claims, Applicants have amended independent claims 1 and 13 to explicitly recite "outputting the classification." "Outputting" of the classification determined by the claimed methods is disclosed in the originally filed application. *See* Application at [0025] and FIG. 4.

Recitation of the "outputting" step explicitly provides that the classification of the differentially expressed genes is available for use by, e.g., a person, program, function, procedure, or other entity. Accordingly, a concrete, useful, and tangible result is provided by the claimed methods and the non-statutory subject matter rejection is overcome.

D. Cancellation of Claim 2 and Amendment of Claim 13

Claims 2 and 13 each originally claimed, in part, "identifying the plurality of differentially expressed genes . . . utilizing . . . a Bonferroni T-test." The recitation of the "Bonferroni T-test" by the claimed methods was an inadvertent error. Claim 2 has been canceled and claim 13 has been amended to remedy this inadvertent error.

CONCLUSION

Applicants believe that these remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the objection to claim 11 and the rejections of claims 1, 3-9, and 11-13 be withdrawn so the claims may swiftly pass to issuance.

Should the Examiner desire to sustain any of the rejections discussed in this Response, the courtesy of a telephone conference between the Examiner, the Examiner's supervisor, and the undersigned agent at 512-536-3027 is respectfully requested in advance.

Respectfully submitted,

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